Section XII: 510(k) Summary of Safety and Effectiveness

MAY - 3 2012

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: Force Medical, Inc.
13566 Freeport Road
San Diego, CA 92129

510(k) FIRM CONTACT: Al Lippincott
BioMedical Engineer
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
allippincott@msn.com

DATE: August 20, 2010

TRADE NAME: Force Medical IM Nail System

COMMON NAME: Intramedullary Nail

CLASSIFICATION: Intramedullary fixation rod *(see 21CFR, Sec. 888.3020)*
Single/Multiple component metallic bone fixation applieances and accesories. *(See 21CFR, Sec. 888.3030)*

DEVICE PRODUCT CODE: **HSB**
SUBSEQUENT PRODUCT CODE: **JDS**

SUBSTANTIALLY EQUIVALENT DEVICES:
Stryker - T2 Ankle Arthrodesis Nail (**K051590, K020384**)
Biomet - Phoenix Nail Systems (**K091976, K081243**)
Wright Medical - Valor Ankle Fusion Nail (**K110552**)

DEVICE DESCRIPTION: The Force Medical IM Nail System is an angled (left & right) and straight (left & right due to hole orientation), cannulated, intramedullary nail in multiple diameters(8) and in multiple lengths(3) manufactured from High Strength 6-4 Titanium Alloy to ASTM F136. The nail features proximal, distal, and midshaft angled hole(s) to receive Alloyed Titanium transverse locking 4.5mm Cortical and 4.5/6.5 Transition Cortical - Cancellous Bone Screws (in various lengths). Endcaps (in 0+ and 6 lengths in 4 diameters) in the Titanium Alloy are available for nail end bottom screw locking and IM Nail length extension. A Titanium Alloy Compression Washer and Screw (in 5 lengths) is also available for joint compression(s) if distal talocalcaneal fusion is required. All alloyed titanium components have a Type II anodize surface treatment and are anodize color coded for left/right versions. A full set of guide/placement instrumentation is available for accurate placement and alignment of the bone screws within the nail when used in conjuction with x-ray fluoroscopy. The system is offered NON-STERILE for single-use.

INTENDED USE: The Force Medical IM Nail is intended for tibiotalocalcaneal (TTC) arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot.

Indications for use include:

- **Posttraumatic and primary Arthrosis**
- **Neuromuscular deformity**
- **Revision of Failed Ankle Arthrodesis**
- **Failed Total Ankle Replacement**
- **Avascular Necrosis of the Talus (requiring tibiocalcaneal arthrodesis)**
- **Neuroarthropathy (Charcot)**
- **Rheumatoid Arthritis with severe deformity**
- **Osteoarthritis**
- **Pseudarthrosis**

BASIS OF SUBSTANTIAL EQUIVALENCY: The Force Medical IM Nail System is substantially equivalent to predicate devices from Stryker, Biomet, and Wright Medical.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS The Force Medical IM Nail System is **substantially equivalent** in Material, Geometry Design/Markings, and Indications to the many predicate systems marketed and sold in the U.S..

SUMMARY OF SAFETY AND EFFECTIVENESS: The Force Medical IM Nail System is shown to be safe and effective for use in IM Nail ankle fusion procedures where stability and precision placement is required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Force Medical, Incorporated
% Engineering Consulting Services, Incorporated
Mr. Al Lippincott
Biomedical Engineer
3150 East 200th Street
Prior Lake, Minnesota 55372

MAY - 3 2012

Re: K102577
Trade/Device Name: Force Medical IM Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDS
Dated: April 10, 2012
Received: April 27, 2012

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: **K102577**

DEVICE NAME: **Force Medcial IM Nail System**

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102577

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)